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Gregory Murphy

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MEYERTONS, HOOD, KIVLIN, KOWERT & GOETZEL, P.C.

P.O. BOX 398

AUSTIN, TX 78767-0398

EXAMINER

SETH, MANAV

ART UNIT

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2624

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/800,461	Applicant(s) MURPHY ET AL.	
	Examiner MANAV SETH	Art Unit 2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 91,92 and 495-498 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 91,92,495-519,521-545,547-571 and 573-597 is/are rejected.
- 7) ☒ Claim(s) 520,546,572 and 598 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/22/05, 1/28/05, 11/2/04, 7/30/04, 7/27/04, 3/15/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 504, 506, 507, 530, 532, 533, 556, 558, 559, 582, 584 and 585 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 506, 507, 532, 533, 558, 559, 584 and 585, applicant claims creating a “second image of the human heart tissue” but in order to have a second heart tissue image there must be a first image created prior to creating a second image. There is no reference to a first image being created in these claims. These claims are vague and indefinite. Please make appropriate correction.

Regarding claims 504, 530, 556 and 582, applicant claims “data derived from **previous** surgical procedures” but there is no reference to previous surgical procedures in the respective claims or in the claims that these claims depend on. The claims are vague and indefinite. Please make appropriate correction.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Art Unit: 2624

The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005), Annex IV, reads as follows (see also MPEP 2106):

Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data.

When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. Compare *In re Lowry*, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure stored on a computer readable medium that increases computer efficiency held statutory) and *Warmerdam*, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) with *Warmerdam*, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory).

In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See *Lowry*, 32 F.3d at 1583-84, 32 USPQ2d at 1035.

4. Claims 92, 521-546 and 573-598 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claims 92, 521-546 and 573-598 defines a carrier medium embodying functional descriptive material (i.e., a computer program or computer executable code). However, the claim does not define a "computer-readable medium or computer-readable memory" and is thus non-statutory for that reason (i.e., "When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized" – Guidelines Annex IV). The scope of the presently claimed invention encompasses products that are not necessarily computer readable, and thus NOT able to impart any functionality of the recited program. The examiner suggests

amending the claim(s) to embody the program on “computer-readable medium” or equivalent; assuming the specification does NOT define the computer readable medium as a “signal”, “carrier wave”, or “transmission medium” which are deemed non-statutory (refer to “note” below). Any amendment to the claim should be commensurate with its corresponding disclosure.

Note:

“A transitory, propagating signal ... is not a “process, machine, manufacture, or composition of matter.” Those four categories define the explicit scope and reach of subject matter patentable under 35 U.S.C. § 101; thus, such a signal cannot be patentable subject matter.” (In re Nuijten, 84 USPQ2d 1495 (Fed. Cir. 2007)). Should the full scope of the claim as properly read in light of the disclosure encompass non-statutory subject matter such as a “signal”, the claim as a whole would be non-statutory. Should the applicant’s specification define or exemplify the computer readable medium or memory (or whatever language applicant chooses to recite a computer readable medium equivalent) as statutory tangible products such as a hard drive, ROM, RAM, etc, **as well as** a non-statutory entity such as a “signal”, “carrier wave”, or “transmission medium”, the examiner suggests amending the claim to include the disclosed tangible computer readable storage media, while at the same time excluding the intangible transitory media such as signals, carrier waves, etc.

Merely reciting functional descriptive material as residing on a “tangible” or other medium is not sufficient. If the scope of the claimed medium covers media other than “computer readable” media (e.g., “a tangible media”, a “machine-readable media”, etc.), the claim remains non-statutory. The full scope of the claimed media (regardless of what words applicant chooses) should not fall outside that of a computer readable medium.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 91, 92, 495-503, 505-509, 511-513, 515-518, 521-529, 531-535, 537-539, 541-544, 547-555, 557-561, 563-565, 567-570, 573-581, 583-587, 589-591 and 593-596 are rejected under 35 U.S.C. 102(b) as being anticipated by Halmann et al., U.S. Patent No. 5,151,856.

Regarding claim 91, Halmann discloses a system configured to assess treatments for disease of a human heart comprising: a CPU and a system memory coupled to CPU, wherein the system memory stores one or more computer programs executable by the CPU (col. 1, line 65 – computerized analysis, where computer apparently being the system and CPU, memory and programs are inherent requirements for the computer system and for a computer system to work these components are inherently required to be coupled to each other), Halmann further discloses performing a first modification of at least one feature of one or more images of heart tissue (abstract, col. 1 line 63 to col. 2 line 2, wherein images of the heart are provided. The heart inherently contains many features such as structural components and by providing the image of the heart these features (structural components) are also provided. Some of these structural components are the coronary arterial system, SA node, AV node, bundle of his, Purkinje Fibers, Atriums, ventricles, bicuspid and tricuspid valves, etc; col. 2, lines 16-21, wherein a angiogram of the coronary artery system is obtained and superimposed onto the image of the heart in the precise location to determine any abnormalities. This superimposing, i.e. read as "a first modification," the coronary

Art Unit: 2624

artery system is read as "performing a first modification of at least one of the plurality of structural elements");

performing at least a second modification of at least one of the features, wherein the second modification is performed independent of the first modification (col. 2 lines 39-51, wherein local regions of the heart are color coded depending on the location of unusual myocardial function, i.e. an abnormality. This color coding, i.e. read as "a second modification," is performed on the heart tissue and it inherently performed on the cardiac tissue walls/structures. The walls form the atriums and the ventricles as well as contain the electrical conducting system/fibers of the heart);

and comparing at least one effect of the first modification to at least one effect of the second modification, or comparing at least one effect of the second modification to at least one effect of the first modification (col. 2 lines 3-51, based on these modifications the function of the heart and any present abnormalities are determined. When the first modification superimposes the coronary structure then this will result in it superimposing the colored areas, i.e. second modification, of the heart since the coronary artery system is covering the whole heart; col. 9, lines 44-53).

Regarding claim 495, Halmann discloses where the first and at least second modifications of at least one feature are compared automatically by at least one of the computer programs based on at least some user input (as discussed in the rejection of claim 91, the process is computerized and initial input by the user is required inherently for any process to be performed by the computer).

Regarding claim 496, Halmann discloses at least one of the features comprises an image (see rejection of claim 91).

Regarding claim 497, Halmann discloses at one of the features comprises at least a portion of an image (see rejection of claim 91).

Regarding claim 498, Halmann discloses at least one of the features comprises a numerical feature (col. 2 lines 39-51, wherein the heart beat/rate is determined and is the feature of the atriums and the ventricles. The heart beat/rate is read as the "numerical feature"; col. 4, lines 62-68 – constructing pulmonary artery which requires calculating the radius of artery, where radius is numerical feature).

Regarding claim 499, Halmann discloses at least one of the features comprises a numerical features derived at least in part from at least a portion of an image (see the rejection of claim 498).

Regarding claim 500, Halmann discloses wherein the first and at least second modifications of at least one feature are compared automatically by at least one of the computer programs by comparing the first and at least second modification of at least one feature to a database (figure element 19 and col. 9, lines 15-22; col. 3, lines 50-65 – the database being the storage/memory).

Regarding claim 501, Halmann discloses the database comprises data derived from expert opinion (col. 3, lines 60 - indicating pathological state of the heart by the system – apparently a person who is expert or specialist in the art of heart analysis (cardiovascular) can only provide such a data to program the computer) .

Regarding claim 502, Halmann discloses dividing at least one image into a plurality of sections (figure element 15 and col. 5, lines 2-6, wherein the sections of the heart images, i.e., read as dividing the heart images, are determined and a segmented cage model formed).

Regarding claim 503, Halmann discloses the database comprises clinical data (figure element 19 and col. 9, lines 16-22, wherein the stored conditions are read as the “clinical data”).

Regarding claim 505, Halmann discloses extrapolating at least one portion of at least one feature from at least two images of human heart tissue (col. 3, lines 8-12 – extrapolating/ estimating the abnormalities by the shape analysis using image slices).

Regarding claim 506, Halmann discloses providing at least two images to the computer system (col. 1, lines 63-67, wherein a plurality of scans are provided. Each scan is read as an image), and using at least two images to create at least a second image of human heart tissue, wherein at least a portion of the second image appears at least three-dimensional (col. 1, line 65- col. 2, line 2).

Regarding claim 507, Halmann discloses providing at least a plurality of images to the computer system (col. 1, lines 63-67, wherein a plurality of scans are provided. Each scan is read as an image), and using at least two images to create at least a second image of human heart tissue, wherein at least a portion of the second image appears at least four-dimensional (col. 2, lines 39- 51 – where the animation being the four dimensional image which apparently includes the time as fourth dimension, since animation is used to measure the variation of heart rates at different times, where heart rate variation of the heart represents physiological factor).

Regarding claims 508 and 509, these claims have been similarly analyzed and rejected as per claim 507.

Regarding claim 511, Halmann discloses creating at least one image of the assessed condition of the heart (col. 2, lines 3-51).

Regarding claim 512, Halmann discloses wherein at least one image of the assessed condition comprises at least a portion appearing three-dimensional (figure elements 20 and 28, col. 2, lines 1-2, and col. 9, lines 15-50).

Regarding claim 513, Halmann discloses wherein at least one image of the assessed condition of the heart comprises progressive coloring (col. 2, lines 39-58; col. 9, lines 5-25 – region color modification of the model representing stress and dysfunction).

Regarding claim 515, Halmann discloses assessing a volume of at least a portion of the heart tissue (As discussed in the claims 506-512- Halmann discloses constructing a 3 and 4 dimensional image and in order to construct such images it being inherent that the volume of the heart tissue is required; col. 4, lines 60-68 – obtaining 3D voxel shape of the organ).

Regarding claim 516, Halmann discloses comparing a contrast between two-or more section in at least one image and assessing a viability of the heart tissue (col. 9, lines 20-28 – for pathological studies such as wall thickness).

Art Unit: 2624

Regarding claim 517, Halmann discloses evaluating motion of at least one portion of at least one feature of one or more images of heart tissue and assessing asynergy for the heart tissue (col. 2, lines 37-38; col. 1, lines 54-60 – a zone of normal coronaries but with mechanical dysfunction; col. 9, lines 55-65; col. 2, lines 40-51 - evaluating heart rates with respect to contractile force; col. 2, lines 3-15 – myocardial function is determined with respect to wall motion and displaying the defective portions).

Regarding claim 518, Halmann discloses evaluating curvature of at least a section of a portion of a heart comprising the heart tissue; and assessing a shape of at least the portion of the heart (col. 4, lines 37-68).

Regarding claim 521-529, claims 521-529 have been similarly analyzed and rejected as per claims 495-503.

Regarding claims 531-535, claims 531-535 have been similarly analyzed and rejected as per claims 505-509.

Regarding claims 537-539, claims 537-539 have been similarly analyzed and rejected as per claims 511-513.

Regarding claims 541-544, claims 541-544 have been similarly analyzed and rejected as per claims 515-518.

Regarding claims 547 and 573, Halmann discloses a system configured to assess treatments for disease of a human heart comprising: a CPU and a system memory coupled to CPU, wherein the system memory stores one or more computer programs executable by the CPU (col. 1, line 65 – computerized analysis, where computer apparently being the system and CPU, memory and programs are inherent requirements for the computer system and for a computer system to work these components are inherently required to be coupled to each other), Halmann further discloses performing a first modification of at least one feature of one or more images of heart tissue (abstract, col. 1 line 63 to col. 2 line 2, wherein images of the heart are provided. The heart inherently contains many features such as structural components and by providing the image of the heart these features (structural components) are also provided. Some of these structural components are the coronary arterial system, SA node, AV node, bundle of his, Purkinje Fibers, Atriums, ventricles, bicuspid and tricuspid valves, etc; col. 2, lines 16-21, wherein a angiogram of the coronary artery system is obtained and superimposed onto the image of the heart in the precise location to determine any abnormalities. This superimposing, i.e. read as "a first modification," the coronary artery system is read as "performing a modification of at least one feature of one or more images of heart tissue"); Halmann further discloses comparing the modification to at least one reference modification in a database to assess an effect of the modification (col. 2, lines 16-25 - assessing or correlating coronary artery pathology and adjacent myocardial dysfunction, col. 3, lines 54-65).

Regarding claims 548 and 574, Halmann discloses where the modifications of at least one feature are compared automatically to a reference modification by at least one of the computer programs based on at least some user input (as discussed in the rejection of claim 547, the process is

Art Unit: 2624

computerized and initial input by the user is required inherently for any process to be performed by the computer).

Regarding claims 549-555 and 575-581, claims 549-555 and 575-581 have been similarly analyzed and rejected as per claims 496-502.

Regarding claims 557-561 and 583-587, claims 557-561 and 583-587 have been similarly analyzed and rejected as per claims 505-509.

Regarding claims 563-565 and 589-591, claims 563-565 and 589-591 have been similarly analyzed and rejected as per claims 511-513.

Regarding claims 567-570 and 593-596, claims 567-570 and 593-596 have been similarly analyzed and rejected as per claims 515-518.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 504, 510, 514, 519, 530, 536, 540, 545, 556, 562, 566, 571, 582, 588, 592 and 597 rejected under 35 U.S.C. 103(a) as being unpatentable over Halmann et al., U.S. Patent No. 5,151,856.

Regarding claims 504, 530, 556 and 582, Halmann et al. does not teach "wherein the clinical data comprises data derived from one or more surgical procedures." This is a well known feature in the art of image processing. Examiner takes OFFICIAL NOTICE. It would have been obvious to one ordinary skilled in the art to incorporate this well known feature. One ordinary skilled in the art would have been motivated to incorporate this feature based on the availability of the hardware and/or software available at the time of invention.

Regarding claims 510, 536, 562 and 588, Halmann as disclosed in the rejection of claim 509 disclosed physiological factor, but Halmann et al. does not teach "wherein at least one physiological factor comprises hormone B-type natriuretic peptide." This is a well known feature which is used on heart failure analysis and examiner takes OFFICIAL NOTICE. It would have been obvious to one ordinary skilled in the art to incorporate this well known feature. One ordinary skilled in the art would have been motivated to incorporate this feature based on the availability of the hardware and/or software available at the time of invention.

Regarding claims 514, 540, 566 and 592, Halmann as disclosed in the rejection of claim 513 disclosed progressive coloring, but Halmann et al. does not teach "wherein progressive coloring comprises grayscale". This is a well known feature in the art of image processing and examiner takes OFFICIAL NOTICE. It would have been obvious to one ordinary skilled in the art to incorporate this well known feature. One ordinary skilled in the art would have been motivated to incorporate this feature based on the availability of the hardware and/or software available at the time of invention.

Regarding claim 519, 545, 571 and 597, Halmann as discussed in the rejection of claim 517 evaluates the motion of the heart tissue to determine the proper functionality of the heart tissue using image analysis (particularly animation). However, Halmann does not explicitly disclose using/assigning a reference point in the images to evaluate the relative movement of the reference points between the two images. This is a well known feature in the art of image processing and examiner takes OFFICIAL NOTICE. It would have been obvious to one ordinary skilled in the art to incorporate this well known feature. One ordinary skilled in the art would have been motivated to incorporate this feature based on the availability of the hardware and/or software available at the time of invention.

9. Claims 520 and 572 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is an examiner's statement of reasons of allowance: the closest prior art (Halmann) does not teach "assessing a mitral regurgitation with a provided velocity of a fluid through at least a portion of the aorta". Claims 546 and 597 would be allowable if rewritten in independent form including all of the limitations of the base claim for the same reasons as applied to claims 520 and 572, after all the 35 USC 101 rejection issues are resolved.

Examiner note: Examiner has cited particular columns and line numbers in the references as applied to the claims above for the convenience of the applicant. Although the specified citations are representative of the teachings for the art and are applied to the specific limitations within the individual claim, other passages and figures may be applied as well. It is respectfully requested from the applicant in preparing responses, to fully consider the references entirely as potential teachings all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the examiner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manav Seth whose telephone number is (571) 272-7456. The examiner can normally be reached on Monday to Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matt Bella, can be reached on (571) 272-7778. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Manav Seth/
Examiner, Art Unit 2624
December 8, 2008